REMARKS

Applicant has amended claims 26 and 27 to recite that the immunostimulatory dosage of the α-interferon composition is about 250,000 U/m^2 to about 500,000 U/m^2 per day. Applicant respectfully requests entry of the above amendments, which raise no new issues that would require further consideration and/or search, and which place the application in better condition for allowance. Applicant thanks the Examiner for the courtesy of a phone interview on February 26, 2003.

Applicant acknowledges the withdrawal of the rejections under 35 U.S.C. §102(e), 35 U.S.C. §103, and 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 8-12, 18, 21, 22, 26, 27 and 30-38 under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner asserted that "there is no teaching in the specification that would allow one to envision the dosage range of "500,000 U/m^2 or less per day and at least about 250,000 U/m^2 per day" and therefore, the amendment to claims 26 and 27 introduces new matter into the specification.

Applicant respectfully disagrees. The specification provides sufficient written description for the range of about 250,000 U/m^2 to about 500,000 U/m^2 per day. As indicated in MPEP §2163.02, the subject matter of the claim need not be described literally in order for the disclosure to satisfy the description requirement. Rather, the disclosure must reasonably convey to the artisan that, as of the filing date, applicant was in possession of the invention as now claimed.

The present specification explicitly discloses that both the broad range of "500,000 U/m^2 per day or less" and the narrower sub-range of "250,000 U/m^2 per day or less" of an α-interferon composition are acceptable in the claimed methods. The present specification also explicitly discloses that the amounts of about 500,000 and about 250,000 U/m^2 per day of an α-interferon composition are acceptable in the claimed methods. See, e.g., page 5, lines 19-26 and page 11, lines 16-20 of the specification. Furthermore, Figures 1 and 2 demonstrate that 250,000 or 500,000 U/m2 of ALFERON-N™ can be used to increase natural killer cell cytotoxicity. Since both the broad and sub-ranges of α-interferon and the specific amounts of α-interferon are

acceptable in the claimed methods, one of ordinary skill in the art would understand that amounts of α-interferon between 250,000 U/m^2 per day and 500,000 U/m^2 per day also would be acceptable for use in the claimed methods. This analysis is supported by *In re Wertheim* 541 F.2d 257, 191 USPQ 90 (CCPA 1976), in which disclosure of a range of "25-60%" and specific examples of "36%" and "50%" was considered sufficient to meet the written description requirement for the range between "35% and 60%." See §2165.05 (III) of the MPEP.

Thus, the specification provides sufficient written description for the claimed range. In view of the above remarks, the Examiner is requested to withdraw the rejection of claims 8-12, 18, 21, 22, 26, 27 and 30-38 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that claims 8-12, 18, 21, 22, 26, 27, and 30-38 be allowed. No fees are due as this response is being filed before the end of the shortened statutory period. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 2/28/03

Monica McCormick Graham, Ph.D.
Reg. No. 42,600

Fish & Richardson P.C., P.A.
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

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Version with markings to show changes made

In the claims:

Claims 26 and 27 have been amended as follows:

26. (Five times amended) A method for stimulating the immune system of a human patient having a non-resectable malignant tumor, said method comprising

a) determining the natural killer lymphocyte cytotoxicity of said patient to provide a baseline natural killer lymphocyte cytotoxicity;

b) administering an immunostimulatory dosage of an α-interferon composition to said patient, wherein said immunostimulatory dosage is about 250,000 U/m^2 to about 500,000 U/m^2 [or less per day and at least about 250,000 U/m^2] per day; and

c) treating said patient with effective non-surgical medical methodologies to diminish said tumor.

27. (Twice amended) A method for stimulating the immune system of a human patient having a resectable malignant tumor, said method comprising:

a) determining the natural killer lymphocyte cytotoxicity of said patient to provide a baseline natural killer lymphocyte cytotoxicity;

b) administering an immunostimulatory dosage of an α-interferon composition to said patient, wherein said immunostimulatory dosage is about 250,000 U/m^2 to about 500,000 U/m^2 [or less per day and at least about 250,000 U/m^2] per day; and

c) surgically resecting said malignant tumor.